

In the Claims:

1-39 (Canceled).

40. (Currently Amended) A stable composition for a benzimidazole derivative, the composition comprising:

- (a) a substrate, said substrate featuring the benzimidazole derivative; and
- (b) a homogenous layer of enteric coating material layered directly over said substrate, without an intermediate layer between said substrate and said enteric coating, said enteric coating material having a pH value of at least about 6.5, ~~thereby obviating the need for an intermediate layer between said substrate and said enteric coating~~, with the proviso that said enteric coating material does not include HPMCP (hydroxypropyl methylcellulose phthalate).

41. (Previously Presented) The composition of claim 40, wherein said substrate is an active core for containing the benzimidazole derivative.

42. (Previously Presented) The composition of claim 41, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.

43. (Previously Presented) The composition of claim 41, wherein said active core is a tablet formed by compression.

44. (Previously Presented) The composition of claim 40, wherein said substrate features:

- (i) a neutral core; and
- (ii) an active coating containing the benzimidazole derivative, said active coating being layered over said neutral core;

such that the composition is in a form of a pellet.

45. (Previously Presented) The composition of claim 44, wherein said active coating includes at least one polymer.

46. (Previously Presented) The composition of claim 45, wherein said at least one polymer comprises hydroxypropylcellulose.

47. (Previously Presented) The composition of claim 45, wherein said at least one polymer comprises hydroxypropyl methylcellulose.

48. (Currently Amended) A stable composition for a benzimidazole derivative, the composition comprising:

- (a) a substrate, said substrate featuring the benzimidazole derivative; and
- (b) an enteric coating material layered directly over said substrate, said enteric coating material having a pH value of at least about 6.5, without thereby obviating the need for an intermediate layer between said substrate and said enteric coating, wherein said enteric coating material includes a combination of hydroxypropyl methylcellulose phthalate (HPMCP) and at least one other enteric coating polymer.

49. (Previously Presented) The composition of claim 45, wherein said active coating includes a basic stabilizing material.

50. (Previously Presented) The composition of claim 49, wherein said basic stabilizing material includes at least one of sodium stearate and arginine.

51. (Previously Presented) The composition of claim 40, wherein said substrate includes a basic stabilizing material.

52. (Previously Presented) The composition of claim 51, wherein said basic stabilizing material includes at least one of sodium stearate, arginine, magnesium carbonate and sodium hydrogen carbonate.

53. (Previously Presented) The composition of claim 40, wherein said substrate features a core containing the benzimidazole derivative, with a suitable binding agent, said core being prepared by spheronisation and pelletization; such that the composition is in a form of a pellet.

54. (Previously Presented) The composition of claim 40, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

55. (Previously Presented) The composition of claim 54, wherein said enteric coating material further comprises an alkaline compound, such that said pH value is adjusted by adding said alkaline compound to said enteric material.

56. (Previously Presented) The composition of claim 55, wherein said alkaline compound is an inorganic alkaline compound.

57. (Previously Presented) The composition of claim 56, wherein said alkaline compound is selected from the group consisting of basic sodium, potassium and ammonium hydroxide.

58. (Previously Presented) The composition of claim 57, wherein said enteric coating material is at least about 60% neutralized by adding said alkaline compound.

59. (Previously Presented) The composition of claim 58, wherein said enteric coating material is at least 80% neutralized by adding said alkaline compound.

60. (Previously Presented) The composition of claim 58, wherein said enteric coating material is at least about 95% neutralized by adding said alkaline compound.

61. (Previously Presented) The composition of claim 55, wherein said pH value is in a range of from about 7 to about 10.

62. (Previously Presented) The composition of claim 55, wherein said enteric coating material further comprises a plasticizer.

63. (Previously Presented) The composition of claim 62, wherein said plasticizer is selected from the group consisting of a citric acid ester and a phthalic acid ester.

64. (Previously Presented) The composition of claim 40, wherein the benzimidazole derivative is selected from the group consisting of Omeprazole,

Pantoprazole, Lansoprazole, Leminoprazole, Perprazole, Rabeprazole, and pharmaceutically acceptable salts thereof.

65. (Currently Amended) A stable composition for a benzimidazole derivative, the composition ~~consisting essentially of comprising:~~:

- (a) a substrate,—said—substrate featuring the benzimidazole derivative; and
- (b) an enteric coating material layered over said substrate, without an intermediate layer between said substrate and said enteric coating, said enteric coating material having a being adjusted to a pH value of at least about 6.5 by an alkaline compound, such that said pH value is adjusted by adding said alkaline compound to said enteric material.

66. (Previously Presented) The composition of claim 65, wherein said substrate is an active core for containing the benzimidazole derivative.

67. (Previously Presented) The composition of claim 66, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet, said active core being formed by embedding the benzimidazole derivative in poloxamer.

68. (Previously Presented) The composition of claim 66, wherein said active core is a tablet formed by compression.

69. (Previously Presented) The composition of claim 65, wherein said substrate features:

- (i) a neutral core; and

- (ii) an active coating containing the benzimidazole derivative, said active coating being layered over said neutral core.

70. (Previously Presented) The composition of claim 69, wherein said active coating includes at least one polymer.

71. (Previously Presented) The composition of claim 70, wherein said at least one polymer comprises hydroxypropyl methylcellulose.

72. (Previously Presented) The composition of claim 70, wherein said active coating includes a combination of hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC).

73. (Previously Presented) The composition of claim 69, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

74. (Previously Presented) The composition of claim 73, wherein said alkaline compound is an inorganic alkaline salt compound.

75. (Previously Presented) The composition of claim 73, wherein said alkaline compound is selected from the group consisting of basic sodium, potassium or ammonium hydroxide.

76. (Previously Presented) The composition of claim 75, wherein said enteric coating material is at least about 60 % neutralized by adding said alkaline compound.

77. (Previously Presented) The composition of claim 76, wherein said enteric coating material is at least about 80 % neutralized by adding said alkaline compound.

78. (Previously Presented) The composition of claim 77, wherein said enteric coating material is at least about 95 % neutralized by adding said alkaline compound.

79. (Previously Presented) The composition of claim 73, wherein said pH value is in a range of from about 7 to about 10.

80. (Previously Presented) The composition of claim 73, wherein said enteric coating material further comprises a plasticizer.

81. (Previously Presented) The composition of claim 80, wherein said plasticizer is selected from the group consisting of a citric acid ester and a phthalic acid ester.

82. (Previously Presented) The composition of claim 64, wherein the benzimidazole derivative is selected from the group consisting of Omeprazole, Pantoprazole, Lansoprazole, Luminoprazole, Perprazole, Rabeprazole, and pharmaceutically acceptable salts thereof.

83. (Currently Amended) A method for producing the preparation of a stable composition for-of a benzimidazole derivative, the method comprising the steps of:

- (a) forming a substrate with the benzimidazole derivative;
- (b) preparing an enteric coating material having a pH value of at least about 6.5; and
- (c) layering said enteric coating material directly over said substrate, without an intermediate layer between said substrate and said enteric coating, with the proviso that said enteric coating material does not include HPMCP (hydroxypropyl methylcellulose phthalate).

84. (Previously Presented) The method of claim 83, wherein said substrate is formed by melting poloxamer and by mixing the benzimidazole derivative into said poloxamer.

85. (Previously Presented) The method of claim 83, wherein said substrate is formed by direct compression.

86. (Previously Presented) The method of claim 83, wherein said substrate is formed by wet granulation.

87. (Previously Presented) The method of claim 83, wherein said substrate is formed by coating on an inert core.

88. (Previously Presented) The method of claim 83, wherein said enteric coating material is prepared by the steps of:

- (i) mixing an enteric material with water to form a mixture; and
- (ii) adding an alkaline compound to said mixture to form an aqueous solution having a pH value of from about 7 to about 10.

89. (Previously Presented) The method of claim 83, wherein said enteric coating material is prepared by the steps of:

- (i) mixing an enteric material with water and alcohol to form a mixture; and
- (ii) adding an alkaline compound to said mixture to form an aqueous solution having a pH value of from about 7 to about 10.

90. (Currently Amended) A stable composition for a benzimidazole derivative, the composition comprising:

- (a) a substrate, said substrate featuring the benzimidazole derivative; and
- (b) a single ~~homogeneous~~ layer of enteric coating material layered directly over said substrate, without an intermediate layer between said substrate and said enteric coating, said enteric coating material having a pH value of at least about 6.5, ~~thereby obviating the need for an intermediate layer between said substrate and said enteric coating~~, with the proviso that said enteric coating material does not include HPMCP (hydroxypropyl methylcellulose phthalate).

91. (New) A stable composition for a benzimidazole derivative, the composition comprising:

- (a) a substrate featuring the benzimidazole derivative; and
- (b) a neutralized enteric coating material layered directly over said substrate, said neutralized enteric coating material having a pH value of at least about 6.5, such that there is no additional layer between said substrate and said enteric coating.